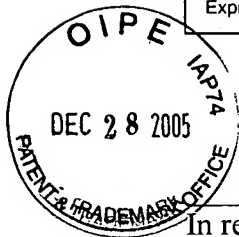


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Docket No.: 01946/100G906-US2
(PATENT)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
William E. Bay et al.

Application No.: 10/615,213

Confirmation No.: 8060

Filed: July 7, 2003

Art Unit: 1625

For: DISODIUM SALTS, MONOHYDRATES,
AND ETHANOL SOLVATES FOR
DELIVERING ACTIVE AGENTS

Examiner: R. J. Desai

INFORMATION DISCLOSURE STATEMENT (IDS)

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

Copies of the documents on the PTO/SB/08 are not provided, since they were previously cited by or submitted to the Office in a prior application number 09/962,794, filed September 24, 2001 and relied upon in this application for an earlier filing date under 35 U.S.C. 120.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as

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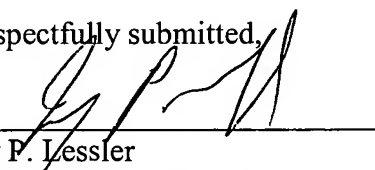
defined in 37 CFR 1.56(a) exists. In accordance with 37 CFR 1.97(h), the filing of this Information Disclosure statement shall not be construed to be an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

Our check in the amount of \$180.00 covering the fee set forth in 37 CFR 1.17(p) is enclosed. The Commissioner is authorized to charge any deficiency of up to \$2,000.00 or credit any excess in this fee to Deposit Account No. 04-0100.

Dated: December 28, 2005

Respectfully submitted,

By 
Jay P. Lessler

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(212) 527-7701 (Fax)
Attorneys/Agents For Applicant



PTO/SB/08a/0 (07-05)

Approved for use through 07/31/2006. OMB 0651-0031
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Substitute for form 1449A/B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/615,213-Conf. #8060
Filing Date	July 7, 2003
First Named Inventor	William E. Bay
Art Unit	1625
Examiner Name	R. J. Desai
Attorney Docket Number	01946/100G906-US2

Sheet 1 of 4

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	AA	3,795,739	3/5/74	Birkmayer et al.	
	AB	3,939,253	2/17/76	Bodor et al.	
	AC	4,035,507	7/12/77	Bodor et al.	
	AD	4,061,466	12/6/77	Sjoholm et al.	
	AE	4,147,767	4/3/79	Yapel	
	AF	4,207,341	6/10/80	Mandfred et al.	
	AG	4,221,815	9/9/80	Weyer et al.	
	AH	4,238,506	12/9/80	Stach, deceased et al.	
	AI	4,239,754	12/16/80	Sache et al.	
	AJ	4,393,192	7/12/83	Curatolo et al.	
	AK	4,442,090	4/10/84	Takeya et al.	
	AL	4,499,299	2/12/85	Bernstein et al.	
	AM	4,462,991	7/31/84	Higuchi et al.	
	AN	4,656,161	4/7/87	Herr et al.	
	AO	4,654,327	3/31/87	Teng	
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	AQ	4,757,066	7/12/88	Shiokari et al.	
	AR	4,835,312	5/30/89	Itoh et al.	
	AS	4,873,087	10/10/89	Morishita et al.	
	AT	4,878,942	11/7/89	Motegi et al.	
	AU	4,900,730	2/13/90	Miyauchi	
	AV	4,927,928	5/22/90	Shroot et al.	
	AW	5,066,487	11/19/91	Morelle et al.	
	AX	5,352,461	10/4/94	Feldstein et al.	
	AY	5,665,700	9/9/97	Cho et al.	
	AZ	5,705,529	1/6/98	Matyus et al.	
	BA	5,447,728	9/5/95	Milstein et al.	
	BB	5,451,410	9/19/95	Milstein et al.	
	BC	5,541,155	7/30/96	Leone-Bay et al.	
	BD	5,629,020	5/13/97	Leone-Bay et al.	
	BE	5,643,957	7/1/97	Leone-Bay et al.	
	BF	5,650,386	7/22/97	Leone-Bay et al.	
	BG	5,709,861	1/20/98	Santiago et al.	
	BH	5,714,167	2/3/98	Milstein et al.	
	BI	5,750,147	5/12/98	Kantor et al.	
	BJ	5,766,633	6/16/98	Milstein et al.	
	BK	5,773,647	6/30/98	Leone-Bay et al.	
	BL	5,776,888	7/07/98	Leone-Bay et al.	
	BM	RE35862	7/28/98	Steiner et al.	
	BN	5,792,451	8/11/98	Sarubbi et al.	
	BO	5,804,688	9/8/98	Leone-Bay et al.	

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				Application Number	10/615,213-Conf. #8060
				Filing Date	July 7, 2003
				First Named Inventor	William E. Bay
				Art Unit	1625
				Examiner Name	R. J. Desai
Sheet	2	of	4	Attorney Docket Number	01946/100G906-US2

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
	BP	5,811,127	9/22/98	Milstein et al.	
	BQ	5,863,944	1/26/99	Leone-Bay et al.	
	BR	5,866,536	2/2/99	Leone-Bay et al.	
	BS	5,876,710	3/2/99	Leone-Bay et al.	
	BT	5,879,681	3/9/99	Leone-Bay et al.	
	BU	5,939,381	8/17/99	Leone-Bay et al.	
	BV	5,958,457	9/28/99	Santiago et al.	
	BW	5,965,121	10/12/99	Leone-Bay et al.	
	BX	5,989,539	11/23/99	Leone-Bay et al.	
	BY	5,990,166	11/23/99	Leone-Bay et al.	
	BZ	6,001,347	12/14/99	Leone-Bay et al.	
	CA	6,051,258	4/18/00	Kantor	
	CB	6,051,561	4/18/00	Leone-Bay et al.	
	CC	6,060,513	5/9/00	Leone-Bay et al.	
	CD	6,071,510	6/6/00	Leone-Bay et al.	
	CE	6,071,538	6/6/00	Milstein et al.	
	CF	6,090,958	7/18/00	Leone-Ba et al.	
	CG	6,099,856	8/8/00	Milstein et al.	
	CH	6,221,367	4/24/01	Milstein et al.	
	CI	6,242,495	6/5/01	Leone-Bay et al.	
	CJ	6,245,359	6/12/01	Milstein et al.	
	CK	6,313,088	11/6/01	Leone-Bay et al.	
	CL	6,344,213	2/5/02	Leone-Bay et al.	
	CM	6,346,242	2/12/02	Leone-Bay et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		EP-0036145	9/23/81			
		GB-2095994	10/13/82			
		EP-226223	6/27/87			
		EP-0365183	10/6/89			
		WO-8807378	10/6/98			
		EP-0576941	6/19/93			
		JP-2239980	9/21/90			
		EP-0517211	9/12/92			
		WO-9747470	12/18/97			
		WO-0007979	5/18/00			
		WO-0006534	2/10/00			
		WO-0006184	2/10/00			

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			Application Number	10/615,213-Conf. #8060	
			Filing Date	July 7, 2003	
			First Named Inventor	William E. Bay	
			Art Unit	1625	
			Examiner Name	R. J. Desai	
Sheet	3	of	4	Attorney Docket Number	01946/100G906-US2

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)				
		WO-0048589	8/24/00			
		WO-0009390	10/12/00			
		ES-369853	7/16/71			
		WO-9929685	6/17/99			
		EP-0225189	10/6/87			

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NON PATENT LITERATURE DOCUMENTS			
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		Picciola G.: "Sintesi Di Acidi Chiazolinioici E. Benzossazonioici E Studio Delle Loro Proprieta Antiniammatore" IT, Societa Chimica Italiana Pavia vol 31, no. 9 pgs 655-664 and English Translation	
		Chem Abs 73548-12-6 (4/1991)	
		Chem Abs 70204-54-5 (4/1991)	
		Chem Abs 184360-83-342 (1975) "Solubility and disassociation constants of some alicyclic acids"	
		Chemical Abstract, Vol. 99(23) Abst. No. 191473h (1983)	
		Riveria, Theresa M. et al. "Oral Delivery of Heparin in Combination with Sodium N-[8-2-hydroxybenzoyl]amino]caprylate: Pharmacological Considerations" Pharmaceutical Research vol 14(12) 1830-1834 (1979)	
		Leone-Bay, A. et al., "The evolution of an oral heparin dosing solution" Drugs of the Future vol 22 (8) 885-891 (1997)	
		Brayden, D. et al. "Heparin Absorption across the intestine; Effects of Sodium N-[8-2-hydroxybenzoyl]Amino] Caprylate in rat in situ intestinal instillations and in Caco-2 monolayers" Pharmaceutical Research vol 14(12) 1772-1779 (1997)	
		Leone-Bay, A. "Acylated non-alpha-amino acids as novel agents for the oral delivery of heparin sodium, USP" Journal of Controlled Release 50: 41-49 (1998)	
		Leone-Bay, A. "4-[4-(2-Hydroxybenzoyl) amino]phenyl]-butyric Acids as Novel Oral Delivery Agent for Recombinant Human Growth Hormone"; Journal of Medicinal Chemistry vol. 39, no 13 pp 2571-2578 (1996)	
		Leone-Bay, A. "N-Acytalated alpha-amino acids as novel oral delivery agents for proteins" ";Journal of Medicinal Chemistry vol 38, 4263-4269 (1995)	
		Leone-Bay, A. "N-Acytalated alpha-amino acids as novel oral delivery agents for proteins" ";Journal of Medicinal Chemistry vol 38, 4257-4262 (1995)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/615,213-Conf. #8060
				Filing Date	July 7, 2003
				First Named Inventor	William E. Bay
				Art Unit	1625
				Examiner Name	R. J. Desai
Sheet	4	of	4	Attorney Docket Number	01946/100G906-US2

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		Ho Koc-Kan; et al. "A Practical Synthesis of ω -aminoalkanoic acid derivatives form Cycloalkanones" Synthetic Communication, vol. 26, no. 14:2641-2649 (1996)	
		Gurrier and Siracusa: "Thermal Condensation of Some alpha-aminoacids with Phthalic Acid" Thermochemica Acta, 7 (1973) 231-239	
		Amino Yusuke et al. Chem Pharm Bull 36 pgs 4426-4434 (1998)	
		Brown et al., J. Med. Chem. 27:79-81 (1984)	
		Johansen, Marianne, et al. "The Kinetics of decompn. Of various N-Mannichi bases of salicylamide" Int. J. Pharm. 1980, 7(2): 119-27 (1980)	
		August 1, 2000 International Search Report issued in connection with PCT Application No. PCT/US00/09390	
		Baughman, R. et al., Circulation (1998), 98 (16) 1610-1615.	

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